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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/439,969	11/12/99	MADHANI	2825.1013002

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LEXINGTON MA 02421-4799

EXAMINER

LEFFERS JR, G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/27/01

Handwritten number 8

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/439,969

Applicant(s)

MADHANI, HITEN D.

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 14-16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 14, 16, 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 15 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Acknowledgment is made of applicants' amendment, filed 1/8/01 as Paper No. 7, in which claims 9 and 15 were amended, claims 10, 12-13 and 17 were canceled, and in which new claim 19 was added. Applicant's election without traverse of Group III (claims 9-13 and 15) in Paper No. 7 is acknowledged. Claims 1-9, 11, 14-16 and 18-19 are pending in this case, with claims 1-8, 14, 16 and 18 being withdrawn from consideration as being drawn towards nonelected inventions.

Any rejection of record from Paper No. 4, mailed 7/5/00, which has not been addressed in this action has been withdrawn. Because new rejections are made in this action which were not necessitated by applicants' amendment, this action is not final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This is a new rejection.**

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The application discloses methods which are dependent upon expression of genes encoding TOT10/YELO33W or PGU1. Neither of these gene sequences is disclosed in the specification. The instant specification describes the TOT10/YELO33W encoding gene as novel. It does not characterize the gene encoding PGU1 beyond describing it as encoding a polygalacturonidase secreted by yeast. The yeast strains from which the PGU1 and TOT10/YELO33W gene sequences were obtained are not clearly described in the specification. Because it is apparent that this biological material (i.e. the gene sequences encoding TOT10/YELO33W and PGU1) is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been

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made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicant's amendment filed 1/8/01.**

Claim 19 is drawn towards a method of identifying an agent which modulates expression of a gene which is modulated by the MAPK pathway, comprising the steps of transforming a suitable host cell with an expression vector comprising a nucleic acid molecule encoding a gene which is modulated by the MAPK pathway under conditions suitable for expression of said gene, contacting the transformed host cell with an agent to be tested, and comparing the expression of the gene in the presence of the test agent to the expression of the gene in the absence of the test agent.

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The phrase “a gene which is modulated by the MAPK pathway” is not clearly defined in the specification. Which MAPK pathway is specified? Only the MAPK pathways in yeast and not in other organisms? If so, does this phrase encompass both the Fus3 or Kss1 mediated pathways, or just the Kss1 pathways? How directly affected by the pathway must a gene be in order to be considered “modulated” by the MAPK pathway (i.e. Tec1 specific modulation or a more global response to the triggering of a MAPK pathway? A reasonable interpretation of the claim as written is that the phrase encompasses any MAPK pathway from any organism as well as any gene whose expression is directly or indirectly affected by the pathway. Thus, claim 19 is an enormously large genus claim with regard to the number of different MAPK pathways from different organisms which are encompassed as well as the even larger number of genes which are affected by these different MAPK pathways.

The specification only describes the MAPK pathways from yeast in any detail. In particular those pathways involving the Kss1 MAPK pathways are described, with Tec1 described as the Kss1 MAPK pathway-specific transcription factor. No other MAPK pathways from other organisms are described in the specification. No other pathway-specific response factors from any other MAPK pathway are described.

Given the large genus of different MAPK pathways from different organisms encompassed by claim 19, the even larger number of genes which can be interpreted as “modulated” by those MAPK pathways, and the lack of description of the genes or response elements involved in any MAPK pathway from any other source other than for the Kss1/Tec1-

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responsive pathways in yeast, one of ordinary skill in the art would not be able to envision a representative number of different embodiments of the claimed genus based upon the description given in the specification. Therefore, one of skill in the art would reasonably conclude that applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 11, 15 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 15 and 19 are vague and indefinite in that the metes and bounds of the term "suitable host cell" are unclear. **This is a new rejection.** This term is inherently indefinite and is likely to vary from investigator to investigator in the absence of an explicit definition in the specification. Therefore, it would be remedial to amend the claim language to clearly indicate what constitutes a "suitable host cell".

Claim 19 is vague and indefinite in that the metes and bounds of the phrase "a gene which is modulated by the MAPK pathway" are unclear (examiner's emphasis). **This is a new rejection necessitated by applicants amendment filed 1/8/01.** The phrase is unclear on at least two grounds. First, a number of different MAPK pathways have been described in vastly

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different cell types from different sources. Even within yeast there are different MAPK pathways, such as ones which feature the Kss1 MAP kinase or the Fus3 kinase. Kss1 MAP kinase itself mediates distinct morphological pathways in yeast. Which MAPK pathway then is referred to by the term "the MAPK pathway". Also, which genes are to be considered as "modulated" by the pathway. Would a gene whose expression is indirectly affected by the pathway (e.g. whose expression is affected by a non-pathway-specific transcription factor activated by pathway "cross talk") be considered a gene "modulated" by the pathway? Or is the term limited to only those genes whose expression is modulated by a "pathway-specific" transcription factor such as Tec1? It would be remedial to amend the claim language to more clearly indicate what is intended by the cited phrase with regard what constitutes "the MAPK pathway" and as to what constitutes gene expression "modulated" by the pathway.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Madhani et al (Science. 2/28/97, Vol. 275, pages 1314-1317; see the entire document).

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The claimed invention is drawn to a method of identifying an agent which modulates the expression of a gene which is modulated by the MAPK pathway. The method comprises transformation of a suitable host cell with an expression vector comprising a gene which is modulated by the MAPK pathway under conditions suitable for expression of the gene, contacting the host cell with a test agent, and comparing expression of the gene in the presence of the agent to expression of the gene in the absence of the agent. The specification teaches that suitable agents for use in the methods of the invention include nucleic acid molecules, polypeptides, proteins, antibodies and small organic molecules.

Madhani et al describe the construction of reporter genes under the control of promoter/regulatory sequences (e.g. FG(TyA)::lacZ, FRE(Ty1)::lacZ or FRE(Tec1)::lacZ) which depend specifically on the MAPK signaling components of yeast that promote filamentous and invasive growth (page 1314, column 3; page 1316, column 1). It was demonstrated that for yeast cells comprising the FRE(Tec1)::lacZ reporter gene, expression of the reporter increased significantly upon expression of the proteins STE11-4 or TEC1 from high-copy plasmids introduced into the cells (e.g. Figure 3).

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R.

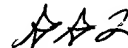
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§ 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Rob Schwartzman, can be reached on (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

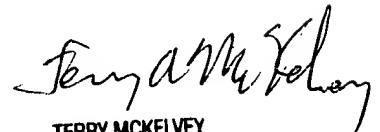


G. Leffers, Jr.

Patent Examiner

Art Unit 1636

March 25, 2001



TERRY MCKELVEY
PRIMARY EXAMINER

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SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).
5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.